



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

MAY 5 1997

Cheryl Radetsky
President
Optimum Lifestyle, Inc.
180 Harbor Drive, Suite 105
Sausalito, California 94965-2845

0009 '97 SEP 19 P1:23

Dear Ms. Radetsky:

This is in response to your letter of March 14, 1997 making a submission to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that you are making the following statements on the label or in the labeling of your product "Lite Bites Antioxidant Advantage™:"

Antioxidant Advantage™ combines a powerful array of vitamins, minerals, proanthocyanidins, and herbal extracts that have the ability to help protect our bodies against destructive molecules called free radicals. Many scientists believe that free radicals play a significant role in the development of many diseases and have a profound negative effect on the aging process.

Section 403(r)(6) of the act makes it clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to prevent and treat diseases. This claim does not meet the requirements of section 403(r)(6) of the act. This claim suggests that this product is intended for use as a drug within the meaning of section 201(g)(1)(B) of the act, and that it is subject to regulation under the drug provisions of the act. If you

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intend to make a claim of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,

James Tanner, Ph.D.
Acting Director
Division of Programs and
Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, San Francisco District Office, Office of Compliance, HFR-PA140
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200



March 14, 1997

Office of Special Nutrients (HFS-450)
Center for Food Safety and Applied Nutrition
200 C Street, S.W.
Washington, D.C. 20204

Re: Section 403(r) (6) Notification

Dear Sir or Madam:

In accordance with the requirements of Section 403(r) (6) of the Federal Food, Drug, and Cosmetic Act, Optimum Lifestyle, Inc. notifies FDA that it has begun using the following statement:

"Antioxidant Advantage™ combines a powerful array of vitamins, minerals, proanthocyanidins, and herbal extracts that have the ability to help protect our bodies against destructive molecules called free radicals. Many scientists believe that free radicals play a significant role in the development of many diseases and have a profound negative effect on the aging process."

on the following product: Lite Bites Antioxidant Advantage™.

Very truly yours,


Cheryl Radetsky
President

RECEIVED BY THE
SPECIAL
NUTRITIONALS, HFS-450



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March 14, 1997

Office of Special Nutrients (HFS-450)
Center for Food Safety and Applied Nutrition
200 C Street, S.W.
Washington, D.C. 20204

Re: Section 403(r) (6) Notification

Dear Sir or Madam:

In accordance with the requirements of Section 403(r) (6) of the Federal Food, Drug, and Cosmetic Act, Optimum Lifestyle, Inc. notifies FDA that it has begun using the following statement:

"Energy Advantage™ combines high-potency standardized Ginseng extracts with superfoods and other energy-enhancing natural ingredients. Research indicates that these ingredients may help naturally increase physical performance and reduce mental fatigue."

on the following product: Lite Bites Energy Advantage™.

Very truly yours,

Cheryl Radetsky
President

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